

## Invited Commentary

# Arterial Bubbles From the Venous Line

The paper by Dickinson et al. assessing the differences in the ability of four manufacturers' extracorporeal circuits (ECC) to remove air entrained into the venous inflow was designed to build on the work by Jones et al. (1) and "rank four commonly employed cardiovascular manufacturer ECC designs."

The finding that there are significant differences in arterial line emboli numbers in the four test circuits following bolus and continuous venous line air entrainment is consistent both with our previous work over the past decade (2-5) and that of others (6-8) demonstrating the varying ability of open cardiopulmonary bypass circuits to remove entrained venous air. However, it is disappointing that the authors have chosen not to identify the circuits tested. The reason for this is not discussed, and blinding of the devices is at odds with the conclusion that the study provides an opportunity for clinicians to potentially minimize the risks of arterial air embolization and make better informed consumer decisions.

This paper addresses important issues regarding in-vitro emboli testing of cardiopulmonary bypass (CPB) circuits. The authors appropriately raise the issue of standards for such testing (a topic recently discussed at the Perfusion Downunder Winter Meeting in Queenstown New Zealand\*) and draw attention to the need for consistency in methodology for investigation of emboli in the CPB circuit. The absence of a gold standard for in-vitro models of CPB make both comparison of studies and new study design difficult.

In all of the studies cited above and the recent study by Rudolph cited by the authors (9), different devices for emboli detection were used. The limitations of Doppler are well known (10). The authors' use of the recently commercially available emboli detection and classification (EDAC) system that uses 5 MHz active SONAR with missile tracking algorithms marks a new era in emboli detection, offering potentially improved sensitivity and specificity over Doppler detection devices.

Other important elements of the in-vitro CPB model for emboli studies are the prime, the method of emboli generation, and the surrogate patient. The latter two present particular challenges.

Emboli generation for in-vitro studies has been the subject of debate (11). Accurate simulation of clinical venous line air entrainment requires air entry through a leak orifice of clinically relevant size, at a rate determined by the size of that orifice and the negative pressure condition in the venous line, rather than by infusion of an arbitrary amount of air at an arbitrary rate from a pump. We have previously described a method for achieving this (3). This is particularly relevant when varying conditions of venous drainage such as vacuum, where fixing the rate of air entry may mask any interaction between the air entry rate, venous line pressure and the number of emboli that appear in the CPB arterial line. The use of a bubble oxygenator as a reliable method of emboli generation described by the authors has not been widely reported. Subject to availability this would appear to provide a widely repeatable model but may fail with respect to the above concerns because it is analogous to a pump and will elute bubbles at a rate that is largely independent of venous line conditions. A possible confounder to emboli numbers in this study is the test reservoir level ( $200 \pm 50$  mL) that is likely below the manufacturers recommended minimum and has been associated with de novo emboli generation in previous generation reservoirs (12).

The use of the membrane oxygenator with the gas phase under vacuum as an in-vitro patient deserves particular attention, as recirculation of emboli in the more traditional in-vitro patient reservoir can be problematic. The approach described in this paper may offer a solution to this difficulty.

The authors describe a novel surrogate for blood. Gaseous emboli in blood become coated with platelets (13) that may result in very different behavior than when present in a non-blood prime (14). While the Food and Drug Administration (FDA) recommends fresh heparinized animal blood (15) for 510 K testing of blood oxygenators, this may not be readily attainable. A separate paper detailing the validation of 28% glycerine blood substitute used in this study is warranted.

The use of new technology embolus detection and innovative techniques to improve the in-vitro circuit for emboli described by the authors not only challenges investigators to achieve some consensus on standardization of test circuit design but also to find solutions to the continuing impact of venous air during CPB.

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\*Emboli in the real world: In-vitro models of CPB. T Willcox, Perfusion Downunder Winter Meeting August 2006.

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